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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,250	07/30/2003	Stephen D. Pacetti	50623.267	9391

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EXAMINER

ZACHARIA, RAMSEY E

ART UNIT	PAPER NUMBER
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1773

DATE MAILED: 07/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/630,250

Applicant(s)

PACETTI ET AL.

Examiner

Ramsey Zacharia

Art Unit

1773

[Handwritten signature]

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/26/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

1. References C2, C4, and C6 have been lined through because copies of these references could not be found in the file.

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 18-20 are rendered indefinite because it is unclear if "R₂-O" in claim 18 represents a non-fouling moiety derived from a hydroxylated functional compound or if "R₂" represents a non-fouling moiety derived from a hydroxylated functional compound as part of a polyether chain (i.e. O represents oxygen units in the chain).

The claims are further rendered indefinite because the polymer formula recited in claim 18 contains an R₃ unit defined as an aliphatic or cycloaliphatic group while the polymer of independent claim 15 also has an R₃ unit having a broader definition.

The claims are further rendered indefinite because it is unclear if the R and R₁ of the polymer recited in claim 18 are identical to the R and R₁ recited in claim 15, chosen from the same group as those of claim 15, or are intended to have a separate definition.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Eury et al. (U.S. Patent 5,605,696).

Eury et al. is directed to a stent coated with a polymer component capable of carrying and releasing therapeutic drugs (column 1, lines 7-12). The polymer may be a polyorthoester (column 4, lines 37-54). A polyorthoester is a polymer formed from the condensation reaction of a diketene acetal and a diol.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-17 and 21-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eury et al. (U.S. Patent 5,605,696) in view of Engelberg et al. (Biomaterials, Vol 12, pages 292-304).

Eury et al. is directed to a stent coated with a polymer component capable of carrying and releasing therapeutic drugs (column 1, lines 7-12). The polymer may be a polyorthoester (column 4, lines 37-54).

Eury et al. do not teach the specific structure of the polyorthoester.

Engelberg et al. is directed to polymers suitable for use in a drug delivery device, including stents (page 292, column 1). Polyorthoesters are cited as particularly useful for controlled release drug delivery (page 293, column 1). The polyorthoester is a the product of condensation reaction between DETOSU and the diols *trans*-cyclohexane dimethanol and 1,6-hexane diol (i.e. hexamethylene glycol) (see Structure 1). DETOSU (i.e. 3,9-diethylidene-2,4,8,10-tetraoxaspiro-[5,5]-undecane) reads on formula I of instant claims 3 and 23 wherein R is an unsubstituted straight-chained C₂ alkyl radical.

Regarding claims 10 and 30, the limitations of these claims are met because the claims, while further limiting the aromatic diols of claims 5 and 25, respectively, do not require the diol to be an aromatic diol.

Regarding claims 11 and 31, the limitations of these claims are met because the claims, while further limiting the organosilicon diols of claims 5 and 25, respectively, do not require the diol to be an organosilicon diol.

Regarding claims 12, 13, 32, and 33, the hexanediol component reads on the hydroxylated functional compound with the cyclohexane diol component reading on the diol. Regarding claims 14 and 34, the compounds recited in these claims (e.g. polyethylene glycol, polypropylene glycol, polytetramethylene glycol) have very close structural similarities and utilities to that taught by Engelberg (polyhexane glycol when "z" is greater than 1). Therefore, it would be obvious to one skilled in the art to replace the polyhexane glycol of Engelberg et al. with one of the compounds recited in claims 14 and 34 since there is an expectation that compounds similar in structure will have similar properties. See MPEP § 2144.09.

Allowable Subject Matter

10. Claims 18-20 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter.

The invention of claim 18 is directed to a medical device having a coating wherein the coating comprises the polymer recited in claim 15. In addition to this polymer, the device further comprises a second polymer as recited in claim 18.

Eury et al. and Engelberg et al. represent the closest prior art. However, neither Eury et al. nor Engelberg teach or fairly suggest a medical device comprising the polymer of instant claim 18 as well as that of instant claim 15.

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Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramsey Zacharia whose telephone number is (571) 272-1518.

The examiner can normally be reached on Monday through Friday from 9 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Thibodeau, can be reached on (571) 272-1516. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Ramsey Zacharia
Primary Examiner
Tech Center 1700